

COMMISSIONER FOR PATENT  
P.O. Box 1450  
Alexandria, VA 22313-1450



Docket No.: 478,1063  
Date: June 10, 2004

In re application of: John N. STANIFORTH, et al.  
Serial No.: 10/621,964  
Filed: July 17, 2003  
For: **COMPOSITION, DEVICE, AND METHOD FOR TREATING SEXUAL DYSFUNCTION VIA INHALATION**

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.  
☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.  
☐ No fee for additional claims is required.  
☐ A filing fee for additional claims calculated as shown below, is required:

FOR:	(Col. 1)		(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
	REMAINING	HIGHEST	PREVIOUSLY	PRESENT	RATE	FEE		RATE	FEE
	AFTER		PAID FOR	EXTRA					
TOTAL CLAIMS	*	Minus 20**	=		x \$ 9	\$		x \$ 18	\$
INDEP. CLAIMS	*	Minus 3***	=	0	x \$ 42	\$		x \$ 84	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ \$140	\$		+ \$280	\$

TOTAL: \$ OR TOTAL: \$

- \* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- ☒ Also transmitted herewith are:  
☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)  
☒ Other: Form PTO-1449 (6 pages); and  
 Complete set of references cited.  
☐ Check(s) in the amount of \$. 00 is/are attached to cover:  
☐ Filing fee for additional claims under 37 C.F.R. 1.16  
☐ Petition fee for extension under 37 C.F.R. 1.136  
☐ Other:  
☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.  
☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.  
☒ Any patent application processing fees under 37 C.F.R. 1.17.  
☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
 Cary S. Kappel, Reg. No. 36,561  
 DAVIDSON, DAVIDSON & KAPPEL, LLC  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited via "hand delivery" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on June 10, 2004.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: \_\_\_\_\_  
 Elizabeth Pietrowski



478.1063

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Not Yet Assigned      Art Unit: 1614  
Re: Application of: John N. STANIFORTH, et al.  
Serial No.: 10/621,964  
Filed: July 17, 2003  
For: **COMPOSITION, DEVICE, AND  
METHOD FOR TREATING SEXUAL  
DYSFUNCTION VIA INHALATION**

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 10, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (6 sheets) for consideration by the Examiner in connection with the above-identified patent application.

Pursuant to 37 C.F.R. § 1.98 (a)(2), the foreign patent documents and non-patent references listed in sheets 1-6 of the attached Form PTO-1449 are enclosed. If it is determined that any of the listed references are not enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent application which is commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/413,022, entitled "Composition, Device and Method for Treating Sexual Dysfunction Via Inhalation", filed April 14, 2003, which the above referenced application is a continuation-in-part of.

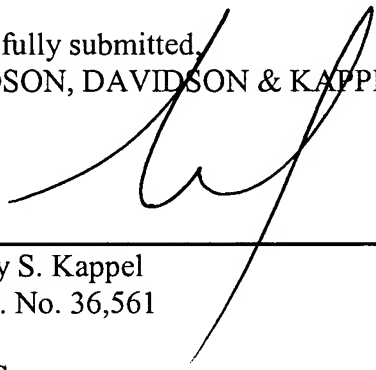
Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner's attention is directed to Exhibit A, attached herewith, which contains the following:

The specification, drawings and pending claims of U.S. Application Serial No. 10/413,022.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (6 sheets) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. In the event any additional fee is due or any overpayment made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Cary S. Kappel  
Reg. No. 36,561

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--FORM PTO-144  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
478.1063SERIAL NO.:  
10/621,964

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):  
John STANIFORTH et al.FILING DATE:  
July 17, 2003

GROUP: 1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4	5	2	1	4	2	1	06/04/85	Foreman	514	267	09/26/83
	AB	4	6	8	7	7	7	3	08/18/87	Neumeyer, et al.	514	280	05/31/85
	AC	5	2	9	2	5	2	0	03/08/94	de Haan, et al.	424	465	08/31/92
	AD	5	4	4	1	7	4	7	08/15/95	de Haan, et al.	424	465	02/09/94
	AE	5	7	5	6	4	8	3	05/26/98	Merkus	514	58	
	AF	5	7	7	0	6	0	6	06/23/98	El-Rashidy, et al.	514	284	10/20/95
	AG	5	9	4	5	1	1	7	08/31/99	El-Rashidy, et al.	424	430	01/30/98

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AH	9	4	2	2	4	4	5	10/13/94	WO (A2)	A61K	31/48		
	AI													
	AJ													
	AK													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AL	Padma-Nathan, "Oral Drug Therapy for Female Sexual Dysfunction", Intl J of Impotence Research, Vol 12 Supp 3 (2000) pp S56 -S57											
	AM	Alexander-Williams, et al., "Novel routes of opioid administration," Brit. J. Anaesth., 1998; 81:3-7											
	AN	van Laar, et al., "Future delivery systems for apomorphine in patients with Parkinson's disease," Parkinson's Disease: Advances in Neurology, Lippincott Williams & Wilkins, Philadelphia, 1999; 80: 535-544.											
	AO	Goldstein, et al., "Vasculogenic female sexual dysfunction: vaginal engorgement and clitoral erectile insufficiency syndromes," Int J Impotence Res, 1998; 10(Suppl. 2) S84-S90.											
	AP	Chustecka, "New treatments for erectile dysfunction", Scrip Reports, PJB Publications Limited, (1998).											
	AQ	Gower et al., "Antagonism of Drug-induced Yawning and Penile Erections in Rats", European J of Pharmac, Vol 122 (1986) pp 239-244											

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 478.1063		SERIAL NO.: 10/621,964						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): John STANIFORTH, et al.								
						FILING DATE: July 17, 2003		GROUP: 1614						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	5	9	9	5	8	6	9	11/16/99	El-Rashidy, et al.	514	284	06/22/98	
	BB	6	9	9	4	3	6	3	11/30/99	El-Rashidy, et al.	514	284	08/24/98	
	BC	6	1	2	1	2	7	6	09/19/00	El-Rashidy, et al.	514	284	06/22/98	
	BD	6	1	9	3	9	9	2	02/27/01	El-Rashidy, et al.	424	430	07/02/99	
	BF	6	2	9	0	5	9	1	03/13/01	Hussain, et al.	424	434	12/10/98	
	BF	6	2	0	0	9	0	3	03/13/01	El-Rashidy, et al.	514	284	11/15/99	
	BG	6	2	9	1	4	7	1	09/18/01	Kling, et al.	514	284	12/17/98	
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BH	9	9	9	9	8	2	8	03/04/99	WO (A1)	A01N	43/42		
	BI													
	BJ													
	BK													
	BL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	BM	Uprima: Scientific Discussion re: Apomorphine in treatment of erectile dysfunction, Abbott Laboratories Ltd. (2001).												
	BN	Summary of Product Characteristics of Apomorphine 2mg and 3 mg sublingual tablets, Abbott Laboratories Ltd. (2001).												
	BO	Heaton et al., "The Characterization of a Bio-Assay of Erectile Function in a Rat Model", J of Urology, Vol 145 (1991) pp 1099-1102												
	BP	Heaton et al., "A Therapeutic Taxonomy of Treatments for Erectile Dysfunction: an Evolutionary Imperative", Intl J of Impotence Research, Vol 9 (1997) pp 115-121												
	BD	Segraves et al., "Effects of Psychotropic Drugs on Human Erection and Ejaculation", Arch Gen Psychiatry, Vol 46 (1989)												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)						APPLICANT(S): John N. STANIFORTH, et al.								
						FILING DATE: July 17, 2003		GROUP: 1614						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL	CA	6	3	0	6	4	3	7	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	6	3	0	6	4	3	7	10/23/01	El-Rashidy, et al.	424	464	06/29/00	
	CB	6	3	4	2	2	5	1	01/29/02	Illum, et al.	424	501	06/02/00	
	CC	6	3	9	5	7	4	4	05/28/02	Adams, et al.	514	284	06/18/99	
	CD	6	4	3	6	9	5	0	05/20/02	Achari, et al.	514	220	06/16/99	
	CE	6	5	1	4	4	8	2	02/04/03	Bartus, et al.	514	220	09/19/00	
	CF	6	5	6	6	3	6	8	05/20/03	El-Rashidy, et al.	514	284	10/23/01	
	CG	6	5	2	9	5	2	1	03/04/03	Ruff, et al.	514	284	11/14/01	
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CH	9	9	2	7	9	0	5	06/10/99	WO(A1)	A61K	9/00		
	CK	9	9	3	8	4	6	7	08/05/99	WO(A1)	A61F	6/06		
	CJ	9	9	6	6	9	0	9	12/29/99	WO(A2)	A61K	31/00		
	CK	9	9	6	6	9	3	3	12/29/99	WO (A1)	A61K	31/505		
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	CM	9	5	2	8	9	3	0	11/02/95	WO (A1)	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	CN	Laduron et al., "Domperidone, a Specific in Vitro Dopamine Antagonist, Devoid of In Vivo Central Dopaminergic Activity", Biochem Pharmac., Vol 28 (1979) pp 2161-2165												
	CO	Bladessarini et al., "Preclinical Studies of the Pharmacology of Aporphines", Basic Pharmac., Vol 1 (1981)												
	CP	Lal et al., "Effect of Domperidone on Apomorphine-Induced Growth Hormone Secretion in Normal Men", J of Neurotransmission, Vol 54 (1982) pp 75-84												
	CQ	Heaton, "Neural and Pharmacological Determinants of Erection", Intl J of Impotence Research, Vol 10 Supp 2 (1998) pp S34-S39												
	CR	Gancher et al., "Peripheral Pharmacokinetics of Apomorphine in Humans", Annals of Neurology, Vol 26 (1989)												
	CS	Heaton et al., "Recovery of Erectile Function by the Oral Administration of Apomorphine", Urology, Vol 45 No 2 (1995)												
	CT	Sachs et al., "Effects of Copulation on Apomorphine-Induced Erection in Rats", Pharmacol Biochem & Behavior, Vol 48 No 2 (1994) pp 423-428												
	CU	"Oral Medication for Impotence", TLC Pharmacy Men's Newsletter, Issue 2												
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*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	DA	5	7	7	0	6	0	6	06/23/98	El-Rashidy	514	284		
	DB	4	0	8	0	4	5	6	03/21/78	Seidemann, et al.	424	258		
	DC	6	4	0	3	6	0	5	06/11/02	Heaton, et al.	514	284		
	DD													
	DE													
	DF													
	DG													
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DH	0	0	7	6	5	0	9	12/21/00	WO(A1)	A61K	31/44		
	DI	0	1	7	4	3	5	8	10/11/01	WO(A1)	A61K	31/4375		
	DJ	0	1	7	6	6	0	2	10/18/01	WO (A1)	A61K	31/473		
	DK	0	1	8	2	9	0	6	11/08/01	WO (A1)	A61K	9/72		
	DL													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	DM	Moyer, Female Sexual Dysfunction, Urch Publishing (August 1998)												
	DN	Lal, et al., "Apomorphine in the Evaluation of Dopaminergic Function in Man," Prog. Neuro-Psychopharmacol. & Biol. Psychiat. vol 12, pp. 117-164 (1988)												
	DO	Harvard Scientific (Harvard Scientific Corp., "Harvard Scientific Acquires Rights to Oral Treatment for Both Male and Female Sexual Dysfunction, pp. 1-3, (Jun. 12, 1998)												
	DP	New Perspectives in Management of Female Sexual Dysfunction: Agenda for Oct. 23-25, 1998 conference in Maine												
	DQ	Essink, et al., "Selective and Quantitative Isolation and Determination of Apomorphine in Human Plasma", J of Chromatography, Vol 570 (1991) pp 419-424												
	DR	Gancher et al., "Absorption of Apomorphine by Various Routes in Parkinsonism", Movement Disorders, Vol 6 No 3 (1991) pp 212-216												
	DS	Lal et al., "Effect of Bromocriptine in Patients with Apomorphine-Responsive Erectile Impotence: An Open Study", J Psychiatr Neurosci, Vol 16 No 5 (1991)												
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	EA													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES      NO				
	EB	0	2	2	4	2	0	2	03/28/02	WO (A1)	A61K	31/44		
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	EE	1	9	99	06	69	0	9	12/29/99	WO(A2)	A61K			
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	EG	0	6	8	9	4	3	8	01/03/96	EP	A61K	31/485		
	EH	1	2	2	6	9	3	3	07/24/02	EP	A61K	31/505		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	EI	Fourcroy, "Issues and Priorities in the Development of Drug Treatments for Female Sexual Dysfunction", International J. Of Impotence Research, 10 Supp 2 (1998)												
	EK	Fernandez-Guasti et al., "Separation of Dopaminergic and Serotonergic Inhibitory Mechanisms in the mediation of Estrogen-Induced Lordosis Behavior in the Rat", Pharm. Biochem. & Behavior, Vol 27 pp 93-98												
	EK	Heaton et al., "Effects of Castration and Exogenous Testosterone Supplementation in an Animal Model of Penile Erection", J of Urology, Vol 151 (1994) pp 797-800												
	EL	Goodman & Gilman, Pharmacological Basis of Therapeutics, 9 <sup>th</sup> Ed. pp 1-9												
	EM	Pehek et al., "Apomorphine and Haloperidol, but not Domperidone, Affect Penile Reflexes in Rats", Pharm Biochem & Behavior, Vol 31 (1998) pp 201-208												
	EN	Danjou et al., "Assessment of Erectogenic Properties of Apomorphine and Yohimbine in Man", Br J clin Pharmac, Vol 26 (1988) 733-739												
	EO	Tagliamonte et al., "Possible Stimulatory Role of Brain Dopamine in the Copulatory Behavior of Male Rats", Pharmac Biochem and Behavior, Vol 2 (1974) pp 257-260												
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*EXAMINER INITIAL	FA	FB	FC	FD	FE	FF	FG	FH	FI	FJ	FK	FL	FM	FN	FO	FP	FD	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
																		11/07/02	Heaton et al.	514	1	05/02/02
																		11/07/02	Achari et al.	514	288	01/31/02
																		12/19/02	Achari et al.	514	295	01/31/02
																		12/19/02	Heaton et al.	514	579	04/22/02
																		01/25/03	Rabinowitz et al.	424	46	05/15/02
																		03/28/02	Edwards et al.	128	203.15	06/08/01
																		01/03/02	Behl et al.	514	282	11/14/01
																		01/03/02	Gupta et al.	514	284	03/29/01
																		11/07/02	Heaton et al.	514	1	05/02/02
																		03/21/02	El-Rashidy et al.	514	321	10/03/01
																		07/04/02	Ruff et al.	514	295	11/14/01
																		09/12/02	Platz et al.	424	46	02/01/02
																		10/31/02	Achari et al.	514	289	01/31/02
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																		01/17/02	Gupta et al.	514	295	03/14/01
																		05/15/03	Heaton et al.	514	288	05/20/02
																		08/22/02	Ruff et al.	514	295	11/14/01
<b>FOREIGN PATENT DOCUMENTS</b>																						
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION								
														YES	NO							
	FR																					
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>																						
	FS																					
EXAMINER										DATE CONSIDERED												
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